UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CARE-TECH LABORATORIES, INC., a corporation; and JOHN C. BRERETON and SHERRY L. BRERETON, individuals, Defendants.	)	Civil Case No: _____

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration, respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Care-Tech Laboratories, Inc., a corporation, and John C. Brereton and Sherry L. Brereton, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

(c) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); (d) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (e) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b)-(c) in that a substantial part of the events and omissions giving rise to these claims occurred in the City of St. Louis, Missouri at Defendant Care-Tech's drug manufacturing facility, where that Defendant resides and can be found.

Defendants

4. Defendant Care-Tech has been incorporated in the State of Missouri since September 5, 1985, and does business at 3224 South Kingshighway Boulevard, St. Louis, Missouri 63139 ("Defendants' facility"), within the jurisdiction of this Court

and within the Eastern Division of the Eastern District of Missouri. Care-Tech is engaged in the manufacture, processing, packing, labeling, holding, and distribution of over-the-counter ("OTC") drug products for human use.

5. John C. Brereton is President and co-owner of Care-Tech. He is responsible for and oversees Care-Tech's purchasing, plant operations, inventory control, building and equipment maintenance, and shipping and receiving. Together with Sherry L. Brereton, Mr. Brereton is responsible for and oversees production, chemistry and quality control, and microbial testing at the firm. Upon information and belief, Mr. Brereton is a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri.

6. Sherry L. Brereton is Vice-President, Secretary, and co-owner of Care-Tech. In addition to the duties she shares with Mr. Brereton, Ms. Brereton is responsible for and oversees Care-Tech's regulatory compliance review, including product labeling, sales, marketing, and finance. Upon information and belief, Mrs. Brereton is a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri.

Defendants' Operations

7. Defendants have been and are now engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing non-sterile, OTC human drug products

using components they received in interstate commerce. Defendants also maintain a website at www.caretechlabs.com, from which customers nationwide can order Defendants' products online or obtain a toll-free number to call and place an order.

8. Defendants' products include a variety of antimicrobial formulations for the treatment and prevention of infection in the elderly, infirm, and other vulnerable patient populations. Defendants' products are "drugs" within the meaning of 21 U.S.C. § 321(g). Defendants introduce their drug products into interstate commerce for shipment outside the state of Missouri.

Defendants' Documented History of Adulteration

9. The Act requires manufacturers of drug products to operate in compliance with current good manufacturing practice ("CGMP") for drugs. 21 C.F.R. pts. 210, 211. FDA's CGMP regulations mandate that manufacturers control the processes and procedures by which drugs are manufactured, processed, packed, and held in order to ensure that drug products have the identity, strength, quality, purity, and other attributes necessary for their safe and effective use. Drugs not made in conformance with CGMP are deemed adulterated as a matter of law, regardless of whether or not they may be deficient in any respect. 21 U.S.C. § 351(a)(2)(B).

10. Defendants have a long history of continuing CGMP violations. Many of the CGMP deficiencies observed by FDA at the

2009 inspection are the same as, or similar to, prior violations observed by FDA during inspections of Defendants' facility that occurred in 2000, 2003, 2005, and 2008. In some inspections, new deficiencies were observed, an indication that the Defendants did not conduct complete assessments after each inspection to assure full CGMP compliance in all areas of their manufacturing operations.

11. Defendants' noncompliance has continued in the face of repeated warnings from FDA regarding their CGMP violations. At the close of each FDA inspection, in 2000, 2003, 2005, 2008, and 2009, investigators issued a detailed List of Inspectional Observations ("Form FDA-483") to Defendants, which notified them of the deviations observed. The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who promised after each inspection to correct the deficiencies. See Exhibits 1-2 hereto, the 2009 and 2008 FDA Form 483s issued to Defendants. The 2009 and 2008 inspections document that Defendants have released and distributed their drug products into interstate commerce without establishing or conducting scientifically sound microbiological testing that will reveal the presence of objectionable microorganisms in their drug products. The inspections found that Defendants have failed to take adequate steps to protect clean equipment from contamination prior to use, for example, by using hoses in direct contact with

the floor and likely contaminated with objectionable microorganisms during manufacturing of their drug products. The 2009 and 2008 inspections also cite Defendants with significant control problems related to manufacturing, facilities, and equipment, resulting in, for example, numerous batches of drug products that were super-potent, sub-potent, or otherwise failed to meet specifications. Some potency problems were caused by uncontrolled temperature and humidity in the compounding room, leading to unpredictable evaporation of the bulk material. Poor handling practices such as adding too much active ingredient to a batch, allowing gallons of drug product to boil over the manufacturing tank, resulted in other potency failures. Although Defendants made some corrections after earlier inspections, they did not follow through on other promises to correct, and the continuing violations demonstrate Defendants' failure to fully assess all of their products, processes, and systems for CGMP compliance and implement comprehensive corrective and preventive actions. FDA investigators continued to observe and document ongoing, serious CGMP violations on each successive inspection of Defendants' facility through 2009.

12. FDA also issued a Warning Letter to Defendants following the 2003 inspection that documented many serious CGMP deficiencies at Defendants' facility, including retesting without investigation, releasing, and distributing into interstate

commerce large portions of "Tech 2000 Dental Rinse" initially found to have heavy microbiological contamination, not rejecting drug products otherwise failing to meet specifications, and failing to establish effective cleaning procedures for manufacturing and filling equipment. The Warning Letter emphasized the serious nature of Defendants' CGMP violations and alerted Defendants that these serious violations of the law could result in the FDA taking further regulatory action without further notice, including "obtaining a court ordered injunction against further marketing of your pharmaceutical products." See Exhibit 3 hereto, the March 23, 2004 FDA Warning Letter. The Warning Letter also reminded Defendants of their responsibility to adhere to all current regulations applicable to their operations. Although Defendants promised to correct the violations detailed in the Warning Letter, some of the same, similar, and new CGMP violations persist.

13. Despite multiple inspections, numerous written warnings by FDA, and Defendants' promises that violations would be remedied, the current CGMP violations observed at Defendants' facility are the same as, or similar to, prior violations observed by FDA and brought to the attention of Defendants.

14. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of

drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

15. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

16. Numerous FDA inspections of Defendants' facility establish that the drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) because the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of Defendants' OTC drug products are not in compliance with CGMP for drugs. 21 C.F.R. pts. 210, 211.

17. FDA's most recent inspection of Defendants' facility took place in May 2009. During that inspection, FDA documented many significant deviations from CGMP. These observations include, but are not limited to, the following:

A. Failure to have laboratory controls that are based on scientifically sound and appropriate specifications, standards, sampling plans, and test procedures to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate

standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

B. Failure to establish and document the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm, as required by 21 C.F.R. § 211.165(e);

C. Failure to conduct appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b);

D. Failure to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a);

E. Failure to follow written production and process control procedures in the execution of the various production and process control functions, failure to document such written production and process procedures at the time of performance, and failure to record and justify any deviation from the written procedures, as required by 21 C.F.R. § 211.100(b);

F. Failure to prepare batch production and control records for each batch of drug product produced that include complete information relating to the production and control of each batch, as required by 21 C.F.R. § 211.188;

G. Failure to establish and follow appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, as required by 21 C.F.R. § 211.113(a);

H. Failure to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, and to extend such investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192;

I. Failure to establish and follow written procedures for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures; failure to review records associated with a representative number of batches, whether approved or rejected, as required by 21 C.F.R. § 211.180(e);

J. Failure to have a quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, as required by 21 C.F.R. § 211.22(a);

K. Failure to maintain a building used to manufacture, process, pack, or hold a drug product in a good state of repair, as required by 21 C.F.R. § 211.58;

L. Failure to have equipment used in the manufacture, processing, packing, or holding of a drug product that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance, as required by 21 C.F.R. § 211.63;

M. Failure to routinely calibrate, inspect, or check automatic, mechanical, or electronic equipment that is used in the manufacture, processing, packing, and holding of a drug product according to a written program designed to assure proper performance, as required by 21 C.F.R. § 211.68(a);

N. Failure to clean, maintain, and as appropriate for each drug, sanitize and/or sterilize at appropriate intervals equipment and utensils to prevent malfunctions or contamination that would affect the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements, as required by 21 C.F.R. § 211.67(a); and

O. Failure to establish a written record of major equipment cleaning, maintenance, and use in individual equipment logs that show the date, time, product, and lot number of each batch processed, as required by 21 C.F.R. § 211.182.

Unapproved New Drugs

18. The Act further requires, subject to an exception described in paragraph 19 below, that drug manufacturers obtain FDA approval of a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to any new drug they introduce into interstate commerce. 21 U.S.C. §§ 331(d), 355(a). A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

19. FDA has established and published regulations, called monographs, that describe certain categories of OTC drugs. 21 C.F.R. pt. 330. OTC drugs manufactured and marketed in conformance with these monographs are generally recognized as safe and effective, 21 C.F.R. § 330.1, and can be introduced into interstate commerce without the submission and approval of an NDA or ANDA.

20. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

21. Defendants are engaged in the manufacture, processing, packing, labeling, holding, and distribution of numerous unapproved new drugs. These unapproved new drugs include, but are not limited to: Barri-Care®, Care-Crème®, Formula Magic®, Humatrix®, Loving Lotion®, Techni-Care®, Tech 2000®, and Urban Skin®.

22. Defendants' drug products, including those listed in paragraph 21, lack an approved NDA or approved ANDA, as required by 21 U.S.C. § 355, and are not exempt from approval under 21 U.S.C. § 355(i).

23. Defendants' drug products, including those listed in paragraph 21, do not conform to any applicable OTC monograph, such as the monograph for Topical Anti-Microbial Drug Products, 21 C.F.R. § 333, or more specifically, the monograph for Topical Antifungal Drug Products, 21 C.F.R. §§ 333.201-280; the monograph for Skin Protectant Drug Products, 21 C.F.R. § 347; or the monograph for Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis, 21 C.F.R. § 358.701-760. For example:

A. Several of Defendants' drug products contain chloroxylenol as an active ingredient and are labeled, represented, and/or promoted to treat dermatitis. No applicable monograph permits use of this ingredient for that indication. To the contrary, FDA has found that there are inadequate data to

establish general recognition of the safety and effectiveness of products containing chloroxylenol for that indication. 21 C.F.R. § 310.545(a)(7), (b).

B. Several of Defendants' drug products contain benzethonium chloride as an active ingredient and are labeled, represented, and/or promoted for use as a topical antifungal or to treat dermatitis. No applicable monograph permits use of this ingredient for those indications. To the contrary, FDA has found that there are inadequate data to establish general recognition of the safety and effectiveness of products containing benzethonium chloride for those indications. 21 C.F.R. § 310.545(a)(7), (a)(22), (b).

C. Further, Defendants' Care-Crème is a new drug because its "transdermal" dosage form is not permitted under any of the applicable monographs. 21 C.F.R. § 310.3(h)(5).

Misbranding

24. The Act also requires that a drug's labeling bear adequate directions for use. 21 U.S.C. § 352(f)(1). For OTC drugs manufactured and marketed pursuant to a monograph, the monograph sets forth the labeling requirements. A drug that fails to bear required labeling is misbranded. Id.

25. Defendants' drug products do not bear the indications, directions, and warnings required by any applicable OTC monographs and are therefore misbranded within the meaning of

21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use. 21 C.F.R. § 330.1.

26. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

27. Defendants also violate 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

28. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold articles of drug are established, operated,

and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA.

II. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

C. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

D. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into

interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that Plaintiff is awarded costs and other such relief as the Court deems just and proper.

Respectfully submitted,

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